OCT 3 1 2012

510(k) Summary: CANOPY™ Laminoplasty Fixation System

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Sarah Marie Fitzgerald
Project Manager, Regulatory Affairs

Date Prepared: June 12, 2012

Device Name: CANOPY™ Laminoplasty Fixation System

Classification: Per 21 CFR as follows:
§888.3050 Spinal Interlaminal Fixation Orthosis
Product Code NQW.
Regulatory Class II, Panel Code 87.

Predicate(s): RELIEVE® Laminoplasty Fixation System (K080664)
Medtronic CENTERPIECE® Plate Fixation System (K050082)
DePuy MOUNTAINEER® Laminoplasty System (K091994)
Synthes ARCH Fixation System (K032534)

Purpose:
The purpose of this submission is to request clearance for the CANOPY™ Laminoplasty Fixation System.

Device Description:
The CANOPY™ Laminoplasty Fixation System consists of spinal fixation plates and screws for use in laminoplasty procedures. CANOPY™ implants are inserted through a posterior cervical or thoracic approach, and are available in various sizes and geometric options to fit individual patient anatomy. Fixation plates may be used with bone graft material. Hinge plates may be used to stabilize a weakened or displaced lamina. Screws are used to attach the plates to bone and are available in a variety of lengths and diameters to fit patient anatomy.

CANOPY™ plates and screws are manufactured from titanium or titanium alloy, as specified in ASTM F67, F136, F1295 and F1472. Optional graft chambers are manufactured from radiolucent polymer as specified in ASTM F2026 and contain tantalum or titanium alloy markers to permit radiographic visualization, per ASTM F67, F136, F560, F1295 or F1472.

Indication for Use:
The CANOPY™ Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The CANOPY™ Laminoplasty Fixation System is used to hold bone allograft material

in place in order to prevent the allograft from expulsion or impinging the spinal cord.

Performance Data:
Mechanical testing (static and dynamic compression, static compression bending and expulsion) was conducted in accordance with ASTM F543 and F2193 and, the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004. Performance data demonstrate substantial equivalence to the predicate device.

Basis of Substantial Equivalence:
The CANOPY™ Laminoplasty Fixation System implants are similar to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 31 2012

Globus Medical, Incorporated
% Ms. Sarah Marie Fitzgerald
Project Manager, Regulatory Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K121732
Trade/Device Name: CANOPY™ Laminoplasty Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: September 28, 2012
Received: October 01, 2012

Dear Ms. Fitzgerald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____

Device Name: CANOPY™ Laminoplasty Fixation System

INDICATIONS:

The CANOPY™ Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The CANOPY™ Laminoplasty Fixation System is used to hold bone allograft material in place in order to prevent the allograft from expulsion or impinging the spinal cord.

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121732